

**Dietary Supplement Stakeholder Meeting  
Food and Drug Administration  
Testimony submitted in behalf of the Nutrition Quackery Prevention Program  
July 20, 1999**

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Good morning. I represent a community-based organization comprised of various members of professional and community associations such as the National Council for Reliable Health Information along with consumer advocates dedicated to the promotion of optimal health through consumer education. The program was initiated in 1986 to address the increasing problem of nutrition related health fraud at the local level.

I want to begin by affirming my commitment to the maintenance of open channels of communication among stakeholders with differing objectives and points of view. If we share a common priority- that of consumer protection and the provision of ethical business practices -then we should naturally be moved to see both sides of an argument presented before establishing a consensus.

Because of time constraints, the questions posed in the Federal Register will be addressed in our written and I'll use the time today to focus on the specific area that we believe needs attention by the Agency.

Experience drawn from 13 years of direct correspondence with the public provides the background for our concern and apprehensions regarding the public's current broad-scale grasp of the dietary supplement issue. We concur with statements made at the June 8<sup>th</sup> meeting in Washington D.C. by the American Dietetic Association (ADA) and the Society for Nutrition Education (SNE) suggesting that consumer's right to access dietary supplements must be complemented by their ability to make FULLY INFORMED CHOICES.

Consumers' belief in the safety and efficacy of dietary supplements is justified by this agency history of strong regulation of these and other similar products. Application of the policy of 'Caveat Emptor' or 'Let the Buyer Beware' with regard to health-oriented items in this country is 'news' to an alarming number of those seeking information from our program.

We see the issue of consumer education strongly associated with criteria # 1 of the four FDA criteria for priority ranking: enhancement of consumer safety and protection. We also support suggestions from both the ADA and the SNE that research be directed towards attaining a better understanding of consumers' attitudes and perceptions, and details related to their decision making process. Data of this nature could then adjunct the Agencies agenda to expand upon their consumer education efforts.

In order to at least establish a level playing field with the present atmosphere created by manufacturers and others looking to stand financial gain from the sales of dietary supplements, consumers need to also be privy to such information as:

- 1) The fact that regulation of these products takes place following the accumulation of AERs. In other words, the public essentially provides the testing ground not the laboratory for new ingredients and new combinations of ingredients.
- 2) That a significant margin for error and inconsistencies exists in the translation between the evidence suggested by scientific investigation and the proposed remedy marketed to reflect those findings.

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- 3) That far more evidence supports the fact that optimal health and well being depends upon the consistent intake of nutrient dense foods (especially darkly pigmented fruits and vegetables) and the long-term adoption of healthy lifestyle practices than that substantiating the use of the majority of the dietary supplements marketed today. People need to be repeatedly advised and reminded of these facts in order to offset their inclination to 'pill-pop' to alleviate health conditions.
- 4) And lastly consumers need to be much more familiar with the evolutionary nature of the scientific process. Here repeated reports announcing conflicting findings or data turn away those who are unfamiliar with the natural patterns associated with science. Armed with such knowledge, an informed public would more likely see the virtue of allowing ample time and patience for the gathering of concrete evidence or simply put - to let science follow its course before taking action in its name.

People need to know these things so that they can truly make FULLY INFORMED CHOICES.

In addressing the Agency's inquiry of suggestions for the proper allocation of limited resources, we propose that the Agency direct some measure of it's efforts toward increasing public awareness and recognition of presently developed resources such as the FDA Consumer Magazine, CFSAN Website and AER Monitoring System, etc. Efforts to broaden the scope of professional and consumer reliance on these resources could prove productive.

Delivering a balanced perspective to the American public entails an active response to the media campaigns funded by a billion dollar business-this means employing the use of higher volume mediums such as public service radio and TV announcements.

We would like to see The Agency actively refute anti-FDA movements and propaganda. Left unchecked, such allegations significantly hinder the Agency's ability to effectively protect consumer interests and secure public confidence.

We, like the ADA and the SNE, support the need for the contents of manufacturer' substantiation files to be publicly accessible.

While we acknowledge the complex issue of delineating between structure/function claims and disease claims, it has been our observation that consumers do not follow these distinctions. Common sense leads to their assumption that a product that "improves circulation" must then play some role in the mitigation of heart disease. Again consumer research is needed to determine whether consumers are able to make meaningful distinctions and to assess their appreciation of this provision of DSHEA which is seemingly done on their behalf.

To conclude, we invite the FDA to join actions taken to heighten consumer's awareness and recognize that doing so is an integral part of assuring consumer safety and protection.

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**Nutrition Quackery  
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July 27, 1999

Janet McDonald, PhD, RD  
U.S. Food and Drug Administration  
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Dear Janet,

The following two pages are the full testimony presented at the Stakeholders Meeting on July 20, 1999. We plan to submit a written comment for the Federal Register in alliance with the Orange County Nutrition Quackery Alert Coalition and other sister organizations by the August 20, 1999 deadline. Please feel free to call for clarification or any further questions.

Thank You,

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